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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,815	02/22/2002	Michael Sworin	2791.1003-007	1636

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/082,815	SWORIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on April 01, 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 57-115 is/are pending in the application.
- 4a) Of the above claim(s) 84-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-77, 79-81 and 83 is/are rejected.
- 7) ☒ Claim(s) 78 and 82 is/are objected to.
- 8) ☒ Claim(s) 57-115 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/1/02, 4/1/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicants' arguments filed April 01, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title has been accepted.
3. The withdrawal of claims 84-115 has been acknowledged.
4. Claims 57-83, Species: A, *in vivo*; B, peptide; C, computationally, are examined on the merits.

### **IDS**

5. The Information Disclosure Statement filed April 01, 2004 has been considered. The Information Disclosure Statement filed October 01, 2002 has been lined through because the references in said Statement are duplicated in the Information Disclosure Statement filed April 01, 2004.

### **OBJECTIONS**

6. Claims 78 and 82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 57-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. NEW MATTER REJECTION.

9. This rejection is necessitated by Applicants amendments.

10. Specific to claim 57, step c), the newly added limitation of “covalent” does not have written description basis support in the pointed to disclosure of page 3, lines 16-20, or page 16, line 26 to page 17, line 2. It is noted the pointed to disclosure does not specify that the covalent binding is to occur “under conditions suitable for covalent binding”. The broad disclosure of “covalent binds” (page 3, lines 16-20, or page 16, line 26 to page 17, line 2); and “ligand...analog are combined under conditions suitable for binding” (page 4, lines 3-5) do not provide adequate written description basis support for the limited limitation of “each analog under conditions suitable for covalent binding”. Claims 58-70 are rejected due to being dependent from claim 57.

#### **CLAIM REJECTIONS - 35 USC § 102**

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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12. Claims 57-63, 65-67, 70-77, 79-81, and 83 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ladner et al. (US 5,223,409 A).

13. This rejection is maintained with respect to claims 57-63, 65-67, 70-77, 79-81, and 83, as recited in the previous office action mailed September 30, 2003.

14. This rejection is necessitated by Applicants amendments.

### **RESPONSE TO ARGUMENTS**

15. Applicant specifically argues that Ladner et al. does not disclose the limitation of claim 57 steps c) and d) wherein a target protein is combined with a macromolecular ligand and each analog under conditions suitable for covalent binding between the target protein and macromolecular ligand. Applicant's argument has been fully considered and found to be unpersuasive as discussed below. Ladner et al. discloses that the novel proteins may be coupled (suitable) directly or indirectly, covalently, or non-covalently, to a label, carrier, or support (column 105, lines 51-54) in vivo analysis (column 112, lines 23-66). Ladner et al. discloses the inter- $\alpha$ -trypsin inhibitor (ITI) (ligand) inhibit both leukocyte and Cathepsin-G activities (target protein) (column 154, lines 59-68). Further, the  $K_i$  for inhibition neutrophil elastase by ITI protein ranges between 60 and 150 nM and values between 20 and 6000 nM (increased inhibition) for the inhibition of Cathepsin G by ITI (column 158, lines 38-54).

### **REJECTION RE-ITERATED**

16. Ladner et al. discloses a method for identifying a compound (inhibitor) (Abstract etc.) comprising "epitope libraries" (analogues) (column 5, lines 63-68 and column 41, lines 20 to column 43, line 10) wherein the protein's constituent segments are held to more or less that conformation (stabilized) unless it is perturbed by denaturant (inert linking group) and if a

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unconstrained peptide has biological activity, the peptide ligand will be in a random coil until it comes into proximity with its receptor (column 26, lines 1-12). The novel proteins may be coupled directly or indirectly, covalently, or non-covalently, to a label, carrier, or support (column 105, lines 51-54) in vivo analysis (column 112, lines 23-66). The dissociation constant is preferably greater than 0.10 uM and P is the binding protein and A or B represent bind ligands (column 15, lines 13-22; and column 16, lines 22-26), as in instant claims 57 and 71, steps a) and b); and claims 58, 70, 72, and 83.

17. The method of Ladner et al. comprises the preparation of variegated population of proteins (analogues); causing the protein to be displayed on the surface; contacting analogues with target material so that potential binding domains and target material may interact; separating from those that do not bind; the population may be used to select for binding to a first target and subsequent targets (column 10, lines 14-68), and the candidate protein must meet specified conditions (column 20, lines 30-54), as in instant claim 1, steps c)-d); claim 71, steps c)-d); claims 59-61, 73-75, and 81.

18. The target molecule is selected from 3D structures derived from computer or theoretical modeling (column 11, lines 59-65), as in instant claims 62, 63, 76, and 77.

19. The method of Ladner et al. is directed to particles that are metabolically inert (column 54, lines 35-36) and cleavable (column 3, lines 25-30); and degradable (column 98, lines 38-40), as in instant claims 65-67, and 79.

20. The binding protein of Ladner et al. has a molecular weight of approximately 23,000 daltons (amu) (column 15, lines 37-39), as in instant claim 80.

### **CONCLUSION**

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. This application contains claims 84-115 drawn to an invention nonelected with traverse, filed July 31, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

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25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly  
5/27/04

*Ardin H. Marschel* 6/7/04  
ARDIN H. MARSCHEL  
TIGMART E. BROWER